## REMARKS

The Office Action dated December 3, 2004, has been carefully considered. It is respectfully submitted that the claims pending in the present application are patentable over the prior art of record for the reasons discussed below. As a preliminary matter, it is pointed out that the claims have been amended in a clarifying manner to recite that it is the functionality of the varicose vein which is destroyed by laser treatment, such destruction of functionality being a consequence of irradiation with laser energy having a specified wavelength in the range of about 1.2 to about 1.8 um.

Claims 1, 2, 6, 7 and 25 have been rejected as unpatentable over Goldman, et al ('084) in combination with Dew et al. The contribution to the art of treating varicose veins made by the inventors of the claimed subject matter includes the wave length of the laser energy used, which is between about 1.2 um to about 1.8 um, i.e., about 1200 nm to about 1800 nm. As stated at page 15, lines 15-22 and page 23, lines 19-23, of the present application, laser energy in the range of about 1200 to 1800 nm is more strongly absorbed in the vessel wall because of the presence of water-containing collagen. This localized absorption minimizes heating of surrounding tissue. In contrast, wavelengths of 810, 940 and 1065 nm are primarily absorbed by hemoglobin in the blood present in the vein, rather than by the wall of the varicose vein. Thus, the heating of the wall of the vein is primarily caused by conduction and connection of heat from the blood and the surrounding tissue is heated to an undesirable extent. Goldman, which makes no mention whatsoever of wavelengths of laser energy and barely any mention of the use of lasers at all, provides no suggestion with regard to the selection of the wavelength of laser energy to be used in treating varicose veins. Thus, Goldman is extremely remote from the claimed subject matter.

There is also no suggestion in either Goldman or Dew (which discloses the use of laser energy having a wavelength of 1320 nm for an entirely different purpose) for combining those references. In fact, as shown by Exhibits A-E attached hereto, the choice by other workers in the varicose vein treatment art of the very wavelengths applicants have found unsatisfactory, i.e., 810, 940, 980 nm, because these other workers believed that it would be desirable to use hemoglobin absorption to perform the treatment is compelling evidence of unobviousness and of the impropriety of attempting to combine Dew with Goldman.

Although Goldman makes passing reference to the use of lasers at column 7, line 57, it is plain that the focus of this patent is on the delivery of RF energy and that Goldman believed his contributions to be (a) the use of a tumescent anesthetic and (b) monitoring the impedance experienced by the energy application device to determine its location within the inner wall of a blood vessel. Thus, Goldman was not concerned, as are applicants here, with the wavelength of laser energy to be delivered and where it would be absorbed. Rather, Goldman is totally silent with regard to the type of laser to be used, the wavelength of the laser energy, where it would be preferentially absorbed, whether the laser energy should be continuous or in bursts, etc. Thus, it is submitted that Goldman does not provide an enabling disclosure with regard to the use of lasers. However, even if Goldman were enabling at some primitive level of laser usage, he sheds no light whatsoever on the type of laser energy which applicants have found to be superior.

In this regard, note that Navarro patent no. 6,398,777 referred to by at page 5, lines 9-16, and elsewhere in the present application, would exemplify what, if anything, was made obvious by the Goldman patent with regard to the use of lasers. This would be, of course, the use of laser energy whose wavelength is 500-1100 nm, which would include the type of energy which is the

dominant wavelength of an Nd:YAG laser of the type disclosed by the Makower reference relied upon by the Examiner, but not that recited in the present claims. Navarro's is precisely the type of laser energy which is seriously deficient as compared with applicants' choice of laser energy in the range of 1200-1800 nm, and preferably 1320 nm. In this regard, it is noted that it is confirmed in the Dew patent at column 6, lines 11-13 that Nd:YAG lasers "will emit light at a fundamental dominant wavelength of 1.06 micrometers." This is the type of wavelength disclosed by Makower and is included in the range disclosed in Navarro which is, as demonstrated herein, much less desirable for use in treating varicose veins than the recited range because it is based on energy absorption by hemoglobin whereas applicants' choice of wavelength is based on energy absorption by water. Stated differently, selection of energy having a wavelength such as those disclosed in Makower and Navarro preferentially treats the contents (blood) of the vessel lumen whereas applicants' choice of wavelength preferentially heats the water in the vessel wall.

Thus, the Goldman reference is profoundly flawed as a reference with regard to the claims in the present application because:

(a) Goldman makes only passing reference to lasers and contains no disclosure whatsoever with regard to the type of laser which could be used.

(b) Given the fact that different types of laser energy have fundamentally different effects when used to treat varicose veins, Goldman lacks an enabling disclosure with regard to the use of lasers for this purpose.

(c) Goldman's emphasis on the use of RF energy is, in effect, a teaching away from the use of lasers which Goldman merely mentions.

In spite of these deficiencies in Goldman, the Examiner has attempted to reconstruct applicants' claims by combining Dew with Goldman. Dew states, at column 5, lines 20-26, that "it has been discovered that application of optical energy to biological tissue, in a nondestructive amount sufficient to generate enough heat to denature the proteinaceous components, can be used to cause the body's own tissues to substantially reproduce the prior tissue structure at a wound or severed tissue site." This is the antithesis of the destruction of the functionality of varicose veins as recited in applicants' claims. In the present invention, the functionality of the veins is to be destroyed, an object which would not be achieved if, as in Dew, the heating were limited to that amount sufficient to denature without being destructive, such that the original tissue would have the capability of reproducing itself. Furthermore, the objective of Dew is to create a "biological glue" by causing collagen to go into solution in order to repair a wound. Thus, while there is no doubt that the Dew does disclose the use of laser energy having a wavelength of approximately 1.32 micrometers, it discloses such usage for a purpose (wound healing) entirely different from that of applicants (destruction of vein functionality) and totally different from the object of Goldman (damage to veins). In light of these facts, it is respectfully submitted that there is absolutely no suggestion in the prior art for combining Goldman and Dew.

Claims 3-5 have been rejected as unpatentable over Goldman in combination with Dew and Roth et al. As stated by the Examiner, Roth discloses a pull back device to be used with a laser which irradiates the prostate urethra. Roth et al. discloses that the device is used to cause undesired tissue to separate from the urethra wall and pass out of the patient's system, but discloses nothing about the type of laser to be used to treat varicose veins. Thus, Roth adds nothing which could cure the fundamental deficiencies in the Goldman and Dew references nor the fundamental deficiency

with regard to the impropriety of combining those references. Furthermore, there is absolutely no suggestion in any of these references for combining Roth with Goldman and/or Dew. This combination of references appears to be nothing more than an attempt to reconstruct the claimed invention. Thus, claims 3-5 are patentable for the reasons stated with regard to claims 1, 2, 6, 7 and 25.

Claim 8 is rejected as unpatentable over Goldman in combination with Dew and Conn. As the Examiner states, Conn does disclose a diffusing tip for a laser for hyperthermia requirement, but nothing with regard to the type of laser to be used to treat varicose veins. Thus, once again, Conn does nothing to cure the deficiencies of Goldman and Dew.

Claims 14-17 and 20-23 have been rejected as unpatentable over Makower in combination with Roth and Dew. The Examiner states that: "Makower et al teach a device as claimed except the particular laser wavelength and the pull back mechanism". However, it is the absence of any teaching with regard to the claimed laser wavelength which makes Makower fundamentally deficient as a reference. This rejection is subject to the same deficiencies as the rejections based on the combination of Goldman and Dew. The wavelength of the energy to be delivered by the recited device is central to the present invention. As acknowledged by the Examiner, Makower does not disclose the recited energy of between about 1.2 and about 1.8 um. The Makower reference does disclose the use of a laser for the destruction of tissue, but is concerned primarily with the tissue in the prostate, not in a varicose vein. Thus, Makower is totally silent with regard to wavelength requirements for laser usage in the treatment of varicose veins.

The attempted combination of Makower with Dew is fatally deficient. As disclosed in the present application, the reason for using 1.32 micrometers rather than 1.06 micrometers is because

the former preferentially heats the water in the collagen of the varicose veins whereas the latter preferentially heats the residual blood which then transmits heat by convection or conduction in a manner which damages surrounding tissue. The disclosure of Dew with regard to the use of laser energy having a wavelength of 1.32 micrometers is for an entirely different purpose. There is no suggestion in the art for combining these references. These references are directed to entirely different objectives, namely, wound healing and treating the prostate and cannot be properly combined. As noted above, the pull back teaching of Roth does nothing to cure this deficiency.

The Examiner's attempt to rely on the teaching in Makower of a Nd:YAG laser as justification for combination with the Dew patent is also at odds with the teaching of Dew. Dew discloses that the dominant wavelength of such lasers is 1.06 micrometers and avoids such use. Thus, if Makower can be considered to suggest anything with regard to wavelength it would be 1.06 micrometers, the dominant wavelength, whereas Dew expressly avoids using that wavelength.

Claim 19 has been rejected as unpatentable over Makower in combination with Dew, Roth, and Conn. As explained with regard to the earlier claims, the rejection based on a combination of Makower and Dew is fundamentally deficient. The disclosure of a diffusion tip in Conn does nothing to cure those deficiencies.

Newly added claims 26-34 simply recite applicant's preferred embodiment of a wavelength of 1.32 um. Thus, these claims are patentable for the same reasons as claims 1-25.

In summary, if one had only the Goldman patent as a starting point for treating varicose veins, he would be directed toward the use of RF energy but he might, in effect, say "what about lasers?" Goldman says nothing about what wavelength of laser to use, but a conventional laser is the Nd:YAG laser which has a dominant wavelength of 1.06. However, as disclosed in the present

application, the use of a laser with such a wavelength would be likely to cause hot spots, perforations, patient pain and other undesirable consequences.

If the Makower reference is used as a starting point, the same chain of reasoning applies, i.e., there is no suggestion of a device using an optic fiber to deliver laser energy at a wavelength between about 1.2 and about 1.8 um for essentially the same reasons as those discussed above with regard to the use of Goldman as a starting point and the combination of Makower with Dew is improper for the same reasons.

In fact, if one surveys the contemporary practices regarding treatment of varicose veins with laser energy, one finds that the overwhelming choice of laser wavelength for use in such treatment is well outside of the claimed range of between about 1.2 and about 1.8 um. Attached hereto as Exhibits A-E are samples of the commercial literature published by Dornier MedTech, biolitec, AngioDynamics, Vascular Solutions and Diomed (the owner of the Navarro patent). We will discuss each in turn.

Dornier MedTech

The Dornier MedTech device uses a wavelength of 940 nm (9.4 um) and expressly states that it is attempting to make use of the absorption characteristics of hemoglobin which it states to be at 940 nm. At both page A-1 and page A-3 of Exhibit A, Dornier MedTech states:

> "The highly unique light of a 940 nm wavelength ensures precise targeting of spider veins (page A-1) /vessels (page A-3) because of its ...
> •Optimal absorption characteristics for hemoglobin (3x more than an 810 or 1064 nm laser)"

Dornier's literature also notes that the absorption characteristics for water at 940 nm are greater than at 810 nm and 1064 nm. However, as can readily be seen from the graph on page A-1,

the absorption characteristics for water are much greater at applicants' claimed range of about 1200 to about 1800 nm. Thus, Dornier considered it more important to base its choice of wavelength on hemoglobin absorption characteristics than on water absorption characteristics.

biolitec

The biolitec commercial literature are attached hereto as Exhibit B. As can be seen, biolitec chooses a wavelength of 980 nm. At page B-3, biolitec says:

> "Since soft tissue contains a high percentage of water and hemoglobin, a laser's light energy must be well absorbed in **both** to cut and coagulate optimally. Considering the absorption characteristics of water and hemoglobin together, 980 nm is the ideal wavelength for soft tissue application—including the ELVeS treatment for superficial reflux of the GSV, which often leads to varicose veins."

In commenting on "other laser wavelengths" at page B-4, biolitec states:

> "Other lasers' wavelengths are either absorbed **too much or too little** in water or in hemoglobin and are consequently limited in several ways."

Thus, once again, biolitec's use of the absorption characteristic of hemoglobin as the dominant parameter in choosing the wavelength of its laser is evidence of the unobviousness of the present claims.

AngioDynamics

Examples of AngioDynamics' varicose veins treatment literature are attached hereto as Exhibit C. As can be seen from page C-2 of Exhibit C, the wavelength chosen by AngioDynamics is 980 nm. This is additional evidence of the unobviousness of applicants' choice of 1200 to 1800 nm.

Vascular Solutions

Examples of Vascular Solutions' commercial literature relating to varicose veins are attached hereto as Exhibit D. At page D-3 of Exhibit D, Vascular Solutions states that its varicose vein treatment kit can operate at wavelengths of 810 nm, 940 nm and 980 nm. Vascular Solutions does not state the reasons for its choice of laser wavelength, but the literature of Dornier and biolitec provide guidance with regard to the reasons for that choice. In any event, the three choices of wavelength made by Vascular Solutions are well outside the range of 1200 to 1800 nm recited in applicants' claims

Diomed

Exhibit E is an example of Diomed's commercial literature relating to laser treatment of varicose veins. As shown on page E-2 of Exhibit E, Diomed uses a diode laser having a wavelength of 810 nm. Once again, this is a wavelength far removed from the wavelengths of about 1200 to about 1800 nm recited in the claims of the present application. This accumulation of evidence of choice of wavelengths other than those claimed by applicants is compelling evidence of unobviousness.

Summary

It is respectfully submitted that the foregoing evidence makes it overwhelmingly apparent that applicants' choice of laser wavelength was not and is not obvious. In this regard, we believe it significant to note that the diode lasers used in the other commercial varicose vein laser treatment products described in the literature attached hereto as Exhibits A-E can be manufactured to produce a wide variety of wavelengths of laser energy. Thus, unlike Makower, each of these commercial

varicose vein treatment companies was not confined to the wavelength produced by a specific type, e.g., Nd:YAG laser, but rather a wide variety of wavelengths was available. With this freedom of choice, these commercial entities focused on the energy absorption characteristics of hemoglobin and chose wavelengths in the range of 810 nm to 980 nm.

What it boils down to is this: The efforts by prior art and contemporary workers to devise a laser treatment for varicose veins has used the energy absorption characteristics of hemoglobin as a guide to choosing the wavelength of the laser to be used whereas applicants have used the energy absorption in the characteristics of water as the primary guide to choice of wavelength. It is respectfully submitted that applicants' departure from the paths traveled by prior art and contemporary workers who had the same objective as applicants is compelling evidence of nonobviousness. Thus, it is believed that the claims of the present application are directed to patentable subject matter.

Applicant's believe that this case is in condition for allowance and a favorable action is respectfully solicited.

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Orrick, Herrington & Sutcliffe's Deposit Account No. **15-0665**.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

Dated: June 23, 2005

By: _____
James W. Geriak, Reg. No. 20,233

ORRICK, HERRINGTON & SUTCLIFFE LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614
949/567-6700 Telephone; 949/567-6710 Facsimile